VIRGINIA BOARD OF MEDICINE Ad Hoc Committee on Office-Based Surgery

Tuesday, July 13, 2010 Department of Health Professions Richmond, VA

CALL TO ORDER: The meeting was called to order by Dr. Stuart Mackler at 10:08 a.m.

ROLL CALL

MEMBERS PRESENT: Stuart Mackler, MD, Chair

Stephen Bendheim, MD
Thomas Clifford, MD
Patrick Clougherty, MD
Gopinath Jadhav, MD
Lewis Ladocsi, MD
Mitchell Miller, MD
Julia Padgett, MD
Barklie Zimmerman, MD

MEMBERS ABSENT: Arnold Beresh, DPM

John Pitman, III, MD

STAFF PRESENT: William L. Harp, MD, Executive Director

Colanthia Morton Opher, Operations Manager Elaine Yeatts, DHP Senior Policy Analyst

Amy Marschean, SAAG

OTHERS PRESENT: Seth Ginther, VAFP

W. Scott Johnson, HDJN & MSV

Tyler Cox, HDJN R. Brian Ball, VSA

Jeremy Greenfield, VHHA

Ralston King, VOS Cal Whitehead, VSEPS Mike Jurgensen, MSV

Matt Benedetti, MB&A/VASPS

Terry Schulte, VAFP Michele Satterlund, VANA Scott T. Vantre, VPMA

EMERGENCY EGRESS INSTRUCTIONS

Dr. Harp provided the Emergency Egress procedures.

INTRODUCTION OF THE PANEL MEMBERS

Dr. Mackler asked the Committee members to introduce themselves and identify the specialty they represented.

- Stuart Mackler, MD –Orthopaedic Surgery, member of the Virginia Board of Medicine
- Stephen Bendheim, MD, Obstetrics and Gynecology
- Thomas Clifford, MD, General Surgery
- Patrick Clougherty, MD, Anesthesiology & Pain Management
- Gopinath Jadhav, MD, Gastroenterology, member of the Virginia Board of Medicine.
- Lewis Ladocsi, MD, Plastic Surgery
- Mitchell Miller, MD, Family Practice
- Julia Konerding Padgett, MD, Dermatology
- Barklie Zimmerman, MD, General and Vascular Surgery

ADOPTION OF THE AGENDA

Dr. Jadhav moved to approve the agenda as presented. The motion was seconded and carried unanimously.

PUBLIC COMMENT ON AGENDA ITEMS

Dr. Mackler acknowledged the public present and invited them to introduce themselves.

Mike Jurgensen, representing the Medical Society of Virginia, spoke in support of the Committee's work and thanked the Board for taking on this charge.

HISTORY OF THE ISSUE AND CHARGE OF THE COMMITTEE

Dr. Harp advised that this Committee grew out of concern surrounding office-based procedures performed with less than desired outcomes. He referred to a letter submitted by Dr. Ladocsi to the Board in 2009 that expressed concern that the current laws and regulations might be insufficient to promote safe practice and prevent misleading advertising. Dr. Ladocsi's letter was discussed at the June 25, 2009 Full Board business meeting, and the Board unanimously agreed that a multi-specialty committee could be formed to further examine the issues. Dr. Harp then provided an overview of the scope of work to be done by the Committee with today's meeting focusing on information-gathering, hearing concerns, determining if a problem exists and, if so, to better define it. He advised the Committee that they are empowered to make a recommendation to the Full Board and then the Full Board can vote to accept, revise or reject the Committee's recommendation.

Dr. Harp then drew everyone's attention to §54.1-100 in the Code of Virginia, and stated that the mission of the Board of Medicine is to protect the public. He stated that the Board exercises its police powers when it is necessary to do so for the preservation of the health, safety and welfare of the public. Dr. Harp then described the licensure and disciplinary processes. He acknowledged that the Board has the authority to issue a general license to practice medicine and surgery which allows for the use of any means or method to prevent, diagnose and treat human physical and mental ailments. Dr. Harp stated that the practitioner should know his/her own limitations and not exceed them in his/her practice. However, when that safeguard doesn't work, the Board may receive a complaint. He explained that the Board's actions are complaint-driven, that complaints come from various sources, and the disciplinary system is basically retrospective. He then gave an outline of the path of a complaint until it reached the Board's office.

ROUNDTABLE LIST OF CONCERNS

Dr. Mackler asked the members to voice their concerns regarding office-based surgery. The major concerns expressed were:

- Insufficient regulation to protect the public
- The qualifications of individuals performing office-based procedures
- Office Staffing
- Adequacy of the operative area/facility
- Individual versus systemic problem
- Unintended consequences of law/regulation
- Hospital review and reporting
- Education of the public
- Patient safety

It was suggested that revising and adding to the existing office-based anesthesia regulations would be one way to address some of the concerns listed above. An alternative view that the existing office-based anesthesia regulations and any new regulations addressing physician qualifications should be treated separately was forwarded as well. It was noted that the existing office-based anesthesia regulations address staffing and facility issues to some extent, they do not address qualifications of the operating physician. Dr. Harp stated that some time after the development of the office-based anesthesia regulations, it was recognized that tumescent anesthesia had not been addressed. This could be done by adding to the existing regulations. Ms. Yeatts suggested that the Board might need to seek additional statutory authority in order to move forward with the development of office-based surgery regulations.

THE VIRGINIA DISCIPLINARY EXPERIENCE

Dr. Harp advised that there hasn't been much activity in the disciplinary realm on office-based surgery. He stated that staff had conducted a search of the Notices and Orders database (approximately 9100) using the terms cosmetic, plastic, office, surgery and liposuction as criteria. The search produced fewer than 10 hits wherein a practitioner was cited for a violation

in the realm of office-based surgery. He stated that it could be concluded that either the search was inadequate, or that there is not an epidemic of unfavorable outcomes with office -based surgical procedures.

BEYOND VIRGINIA

Dr. Ladocsi provided the Committee with a summary of how other states regulate office-based anesthesia and surgery from his review of the material provided to the Committee in the agenda packet. He advised the Committee that he makes no guarantees about the accuracy of the following:

- 26 states have no regulations, rules, statutes or advisories addressing outpatient surgery.
- 8 states address the provider and the facility: AL, CA, CO, FL, LA, MA, NJ, NY
- 14 states address the facility: AZ, CT, DE, KS, KY, MS, OH, OK, OR, SC, TN, TX, VA, WA
- 3 states address the provider: IL, IN, NC
- 3 states have specific mention of liposuction: FL, MS, OH
- 5 states require physicians who want to perform outpatient surgery to have ABMS board certification or hospital privileges to perform those procedures: CO, FL, LA, NC, MS
- 1 state requires CRNAs providing general anesthesia to be supervised by an anesthesiologist: IL
- 1 state requires physicians performing outpatient surgery to have hospital admitting privileges: IN
- 2 states require outpatient surgery to be performed in accredited facilities: OH, OR
- 3 states deem failure to comply with outpatient surgery regulations as unprofessional conduct: CA, LA, NJ
- 1 state has an alternate pathway for non-boarded physicians to be licensed to perform outpatient surgery: NJ

The Committee also discussed the Florida experience that resulted in a prohibition on some procedures and the subsequent regulations on outpatient surgery put in place by the Florida Board of Medicine. It was noted that 46 deaths related to outpatient procedures from the period of January 2000 to January 2006 were reported. As a result, outpatient surgery facilities were shut down for six months which significantly impacted health care delivery in the state. The Committee members agreed that this bit of history should be considered by Virginia as it discusses what should be the acceptable standard for anyone performing office-based surgery.

NEXT STEPS

In preparation for the next meeting, Ms. Yeatts requested that the Committee members forward their thoughts, concerns, and suggestions about what they believe can be done to address these issues. The communications, along with material gathered from other states, and other research, will be pulled together and distributed to Committee members. In advance of the next meeting, Dr. Miller commented that this approach will facilitate informal brainstorming and discussion with interested parties in their communities, organizations, and specialties.

The next Committee meeting will be scheduled in October or November	
With no other business to conduct, th	ne meeting adjourned at 12:05 p.m.
Stuart Mackler, MD, Chair	William L. Harp, M.D. Executive Director
Colanthia M. Opher Recording Secretary	